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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,467	06/24/2002	Kenneth D. Tew	FCCC.99-08US	8802
110	7590	09/30/2004	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			NICHOLS, CHRISTOPHER J	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,467

Applicant(s)

TEW ET AL.

Examiner

Christopher J Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 5,8-10 and 17-25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-13 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6 and 14-16 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7.22.02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-4, 6, 7, and 11-16) in the reply filed on 25 June 2004 is acknowledged. The traversal is on the ground(s) that the restriction requirement is improper for failure to comply with the terms of 35 U.S.C. §371 for the following reasons: **(a)** no Lack of Unity was established in the international stage of the instant application, **(b)** the Examiner improperly applied the rules of Lack of Unity, **(c)** all components of an independent claim must be examined together, and **(d)** all the products for the six groups are the same. This is not found persuasive because the International Search Report, Written Opinion, and International Preliminary Examination Report are all considered advisory actions and have no bearing on the prosecution of the application once it enters the national stage. Further, all six groups as set forth in the previous Office Action (25 March 2004) do not share a special technical feature. Also, restriction (as well as Lack of Unity) is between inventions not claims. The six groups all differ in their classification, their search fields, and their special technical features. As such restriction between the six groups is considered proper and is hereby maintained. Claims **5, 8-10, and 17-25** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 25 June 2004. The requirement is still deemed proper and is therefore made FINAL.

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Status of Application, Amendments, and/or Claims

2. The Submission of Sequence Listing and Amendment filed on 9 August 2004 has been received and entered in full.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

4. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *an isolated nucleic acid comprising the sequence of SEQ ID NO: 1 encoding a human ABCA2 transporter protein about 2436 amino acids in length, said*

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encoded transporter protein comprising a multi-domain structure including a multiplicity of glycosylation and phosphorylation sites, a lipocalin signature motif, nucleotide binding folds having Walker A and B ATP binding sites, and a plurality of membrane spanning helices, does not reasonably provide enablement for amino acids encoded by allelic variants of the sequence of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **make** or **use** the invention commensurate in scope with these claims.

6. The claims are drawn very broadly to isolated nucleic acids comprising the sequence of SEQ ID NO: 1, nucleic acids which hybridize to said sequence, and allelic variants thereof.

7. The specification teaches that the nucleic acid of the sequence of SEQ ID NO: 1 encodes a protein of the amino acid sequence of SEQ ID NO: 2 which is a human ABCA2 transporter.

8. However, the specification fails to provide any guidance for the successful manufacture or use of allelic variants of the nucleic acid sequence of SEQ ID NO: 1. And since resolution of the various complications in regards to the use and manufacture of what constitutes an allelic variants of the nucleic acid sequence of SEQ ID NO: 1 is highly unpredictable, one of skill in the art would have been unable to practice the invention without engaging in undue trial and error experimentation. In order to practice the invention using the specification and the state of the art as outlined below, the quantity of experimentation required to practice the invention as claimed would require the *de novo* determination of formulations of allelic variants of the nucleic acid sequence of SEQ ID NO: 1. In the absence of any guidance from the specification, the amount of experimentation would be undue, and one would have been unable to practice the invention over the scope claimed.

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9. Additionally, a person skilled in the art would recognize that predicting the efficacy of manufacture of allelic variants of the nucleic acid sequence of SEQ ID NO: 1 based solely on its prophetic suggestion is highly problematic (see MPEP §2164.02). Thus, although the specification prophetically considers and discloses general methodologies of using and making the allelic variants of the nucleic acid sequence of SEQ ID NO: 1, such a disclosure would not be considered enabling since the state of protein biochemistry is highly unpredictable and complex. The factors listed below have been considered in the analysis of enablement [see MPEP §2164.01(a) and *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)]:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

10. The following references are cited herein to illustrate the state of the art of ABCA2 and protein biochemistry.

11. On the breadth of the claims, Broccardo *et al.* (6 December 1999) “The ABCA subclass of mammalian transporters.” Biochim Biophys Acta. **1461**(2): 395-404 (**IDS #C1**) teaches that the ATP-binding cassette (ABC) transporters are one of the largest gene families. Broccardo *et al.* estimate that the human genome alone may contain more than 1000 ABC genes (pp. 396).

Each subclass within the superfamily has its own characteristics and as such the Specification as filed fails to provide adequate teachings of what constitutes an “allelic” variant or which motifs must be conserved. For instance, 4 ABCA transporters have been fully characterized but 11

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ABCA-encoding genes have been identified (Table 1). Thus the claims as instantly presented represent an invitation to experiment. First to identify, then clone, and then characterize as of yet unidentified “allelic” variants of the instantly claimed nucleic acid (gene).

12. On the nature of the invention, Zhao *et al.* (15 September 2000) “Cloning, characterization and tissue distribution of the rat ATP-binding cassette (ABC) transporter ABC2/ABCA2.” Biochem J. **350**(Pt 3): 865-72 teaches the cloning, functional characterization, and tissue distribution of ABC2/ABCA2, which belongs to the ABC1 subfamily. Rat ABC2 shares 44.5%, 40.0%, and 40.8% sequence homology with mouse ABC1/ABCA1, human ABC3/ABCA3, and human ABCR/ABCA4 respectively (Figure 1). Therefore it is unclear whether the limitation of “allelic variants” encompasses different species, different tissues, different developmental stages, and/or splice variants of a single parent gene. And as such the claims as instantly presented are an invitation to experiment. First to identify the gene hybridizing or “allelic” variant of the polynucleotide of SEQ ID NO: 1, to isolate, characterize, and then determine if it falls within the scope of the claims.

13. On the level of predictability in the art, especially “allelic variants” of the nucleic acid of the sequence of SEQ ID NO: 1, the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein’s sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein’s structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct

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three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions [see Wells (18 September 1990) "Additivity of Mutational Effects in Proteins." Biochemistry **29**(37): 8509-8517; Ngo *et al.* (2 March 1995) "The Protein Folding Problem and Tertiary Structure Prediction, Chapter 14: Computational Complexity Protein Structure Prediction, and the Levinthal Paradox" pp. 433-506]. However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Although the specification outlines art-recognized procedures for producing and screening for active muteins, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone [Bork (2000) "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle." Genome Research **10**:398-400; Skolnick and Fetrow (2000) "From gene to protein structure and function: novel applications of computational approaches in the genomic era." Trends in Biotech. **18**(1): 34-39, especially p. 36 at Box 2; Doerks *et al.* (June 1998) "Protein annotation: detective work for

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function prediction.” Trends in Genetics **14**(6): 248-250; Smith and Zhang (November 1997) “The challenges of genome sequence annotation or ‘The devil is in the details’.” Nature Biotechnology **15**:1222-1223; Brenner (April 1999) “Errors in genome annotation.” Trends in Genetics **15**(4): 132-133; Bork and Bairoch (October 1996) “Go hunting in sequence databases but watch out for the traps.” Trends in Genetics **12**(10): 425-427]. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

14. Thus the specification of the instant application fails to provide adequate guidance for one of skill in the art to overcome the unpredictability and challenges of applying results from prophetic suggestion to the use and manufacture of allelic variants of the nucleic acid sequence of SEQ ID NO: 1 as exemplified in the references herein.

15. Claims **1-4** and **6** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

16. The claims are drawn to polynucleotides that hybridize with a particular disclosed sequence or are allelic variants. The claims do not require that the polynucleotide possess any particular conserved structure, or other distinguishing feature, such as a specific biological activity. Thus, the claims are drawn to a genus of polynucleotides that is defined by possible hybridization or hypothetical genetic relation via alleles.

17. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is in the form of a recitation of possible hybridization or unspecified allelic variation. The specification does not identify any particular portion of the structure that must be conserved, nor does it provide a disclosure of structure/function correlation. The distinguishing characteristics of the claimed genus are not described. The only adequately described species is a polynucleotide comprising the sequence of SEQ ID NO: 1. No active variants are disclosed. Accordingly, the specification does not provide adequate written description of the claimed genus.

18. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at

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page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

19. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

20. Therefore, only isolated nucleic acids comprising the nucleic acid sequence set forth in SEQ ID NO: 1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision.

21. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

22. The term "specifically hybridizes" in claim 4 is a relative term which renders the claim indefinite. The term "specifically hybridizes" is not defined by the claim, the specification does

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not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

23. To satisfy the requirements of 35 U.S.C. §112 ¶2 Applicant must unambiguously define the limitations of the claims. For example, “stringent conditions” for hybridization, while known in the art, are not unambiguously defined. A great deal of latitude and a range of conditions may be construed as “stringent” or “specific”. Also, stringency may be low, moderate, or high, none of which is specified by the claims as instantly neither presented nor supported by the Specification.

24. For instance, the Roche website defines hybridization conditions under four parameters: temperature, pH, concentration of monovalent cations, and the presence of organic solvents, none of which are defined by the claims or the Specification (“Nucleic Acid Hybridization-General Aspects” pp. 33-37 Roche website retrieved on 12 May 2004). Also the NIH Division of Intramural Research teaches that “Nucleic Acid Hybridization” conditions vary. For temperature it teaches that it may be 25°C below duplex melting temperature, which varies due to the length of the polynucleotide and the GC content. Also, salt concentrations may vary between 5 to 6x SSC and denaturing agents such as formamide ranges from 1% to 50% (NIH Division of Intramural Research “Nucleic Acid Hybridization” retrieved from NIH website on 12 May 2004).

25. Furthermore Umansky *et al.* US 6,287,820 states:

Numerous equivalent conditions can be employed to comprise either low or high stringency conditions; factors such as the length and nature (DNA, RNA, base composition) of the probe and nature of the target (DNA, RNA, base composition, present in solution or immobilized, etc.) and the concentration of the salts and other components (e.g., the presence or absence of formamide, dextran sulfate, polyethylene glycol) are considered and the hybridization solution can be varied to generate conditions of either low or high stringency hybridization different from, but equivalent to, the above listed conditions.

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The term "hybridization" as used herein includes "any process by which a strand of nucleic acid joins with a complementary strand through base pairing" (Coombs, Dictionary of Biotechnology, Stockton Press, New York N.Y. [1994].

"Stringency" typically occurs in a range from about $T_m - 5^\circ\text{C}$. (5. degree. C. below the T_m of the probe) to about 20°C . to 25°C . below T_m . As will be understood by those of skill in the art, a stringent hybridization can be used to identify or detect identical polynucleotide sequences or to identify or detect similar or related polynucleotide sequences.

26. Therefore, stringent hybridization can be used to detect similar or related polynucleotide sequences, but there is no definite limit as to how similar or related the polynucleotide sequences have to be, and the claims are indefinite.

27. Therefore the skilled artisan is not apprised of the metes and bounds of what constitutes "specifically hybridizes". Neither the specification nor the art defines the term unambiguously. Thus the metes and bounds of the claims cannot be determined. Incorporation of those conditions which Applicant feels defines the term "specifically hybridizes" into the claims would obviate the rejection.

28. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the limitation "allelic variants" are not clearly defined in the Specification or the prior art. It is not clear whether it defines species, tissues, developmental stages, and/or splice variants of a single parent gene. Thus the metes and bounds of the limitation are not clear.

29. Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. It is not clear if the claimed host cells must be isolated or if they encompass host cells in the context of multicellular organisms (including humans). Further the claims fail to specify if a nucleic acid not comprising SEQ ID NO: 1 was transformed into the cell or whether it is endogenous to the cell.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

30. Claims 4 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Kikuno *et al.* (30 June 1999) “Prediction of the coding sequences of unidentified human genes. XIV. The complete sequences of 100 new cDNA clones from brain which code for large proteins in vitro.” DNA Res. 6(3): 197-205.

31. Kikuno *et al.* teaches a nucleic acid that shares 100% homology to instantly claimed the polynucleotide of SEQ ID NO: 1 from bp 2030 to bp 8040 thus meeting the limitations of a “gene specifically hybridizing” and “allelic variants” of claims 4 and 6.

32. Claims 4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Luciani *et al.* (1 May 1994) “Cloning of two novel ABC transporters mapping on human chromosome 9.” Genomics 21(1): 150-9 (IDS #C3).

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33. Luciani *et al.* teaches a nucleic acid that shares 70.1% homology to instantly claimed the polynucleotide of SEQ ID NO: 1 which encodes an amino acid that shares 90.6% homology to the polypeptide of SEQ ID NO: 2 thus meeting the limitations of a “gene specifically hybridizing” and “allelic variants” of claims 4 and 6 (Figure 4).

Summary

34. Claims **11-13** are free of the art.

35. The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon for the instant rejection(s) are considered pertinent to the instant application:

a. US Patent Application No. 2002/0169137

(teaches a sequence with 100% homology to SEQ ID NO: 1)

b. US Patent Application No. 2002/0068710

(teaches a sequence with 99.9% homology to SEQ ID NO: 1)

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
September 23, 2004



ELIZABETH KEMMERER
PRIMARY EXAMINER